In the United States Court of Federal Claims

No. 20-499C

(Filed: December 30, 2020)

GILEAD SCIENCES, INC. Plaintiff, **v.** **UNITED STATES,** Defendant.	Suit based on alleged breach of contracts; motion to dismiss in which government points to defenses asserted by plaintiff in earlier action filed by government against plaintiff; 28 U.S.C. § 1500; pleading a claim

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OPINION AND ORDER

LETTOW, Senior Judge.

This case arises out of five contracts between plaintiff, Gilead Sciences, Inc. ("Gilead"), and the Centers for Disease Control and Prevention ("CDC"), acting on behalf of the federal government.[1] These contracts consist of four Material Transfer Agreements ("MTAs") and one Clinical Trial Agreement ("CTA"). Gilead and the CDC entered into these agreements as part of an ongoing collaboration on research "relating to the use of antiretroviral agents for prevention of HIV-1." Compl. ¶ 4. Gilead alleges that "the [g]overnment is asserting patents that it secretly obtained in violation of the collaboration agreements," Compl. ¶ 2, and that "[t]he [g]overnment

[1] References to the "United States," the "government," and the "CDC" all refer to defendant and its collective entities.

breached its obligations under both the MTAs and the CTA," Compl. ¶ 10. The context in which this case arises includes a suit filed by the government against Gilead for infringement of the relevant patents. *See United States v. Gilead Sciences, Inc*., No 19-2103MN (D. Del., filed Nov. 6, 2019). That action was instituted approximately five months before Gilead filed this suit.[2]

Pending before the court is the government's motion to dismiss the complaint pursuant to Rules 12(b)(1) and 12(b)(6) of the Rules of the Court of Federal Claims ("RCFC"). *See* Def.'s Mot. to Dismiss ("Def.'s Mot."), ECF No. 11. After briefing, *see* Pl.'s Resp. to Def.'s Mot. ("Pl.'s Resp."), ECF No. 12; Def.'s Reply to Pl.'s Resp. ("Def.'s Reply"), ECF No. 15; Pl.'s Sur-Reply to Def.'s Reply ("Pl.'s Sur-Reply"), ECF No. 18, the court held a hearing on Monday, December 14, 2020. The government's motion to dismiss this action is based on lack of subject-matter jurisdiction and failure to state a claim. *See* Def.'s Mot. at 2.

The court concludes that Gilead's claims for breach of contract are timely under 28 U.S.C. § 2501, as they accrued within six years of Gilead's filing suit in this court. Furthermore, Gilead's claims are not barred by 28 U.S.C. § 1500 because Gilead has only asserted defenses in the Delaware action, and relatedly the statute speaks in terms of a "claim," not a defense. Lastly, Gilead has pled viable breach of contract claims to avoid dismissal under RCFC 12(b)(6). Accordingly, the government's motion is DENIED.

BACKGROUND[3]

Gilead "has brought to market more than a dozen products that have been approved by the FDA for the treatment and prevention of HIV." Compl. ¶ 28. The company "has a long history of working with the scientific community," including the CDC, "to promote basic scientific and clinical research on HIV, HIV treatment, and HIV prevention." Compl. ¶ 39. The collaborations between Gilead and the CDC have taken the form of "many material transfer and related agreements over the past three decades." Compl. ¶ 42.

The MTAs at issue in this case span from 2004 to 2014. Compl. ¶ 44. In each of these MTAs, "Gilead agreed to provide" certain compounds to the CDC "at no cost, to be used in HIV-1 research." Compl. ¶ 45. "[U]nder each of the four MTAs," Compl. ¶ 45, the government agreed to, *inter alia*, "promptly notify" Gilead of "any Inventions" derived from work performed under the agreements. *E.g.*, Compl. Ex. 4 at 3. Each MTA defined "Inventions" as "any inventions, discoveries, and ideas that are made, conceived or reduced to practice." *E.g.*, Compl. Ex. 4 at 3. The government also agreed "to give serious and reasonable consideration to [Gilead's] request for a non-exclusive or exclusive license on commercially reasonable terms under [the government's] intellectual property rights in or to any Inventions." *E.g.*, Compl. Ex. 4 at 3. The MTAs at issue were amended as the collaborations progressed. *See, e.g.*, Compl. Ex. 8.

[2] This case was filed on April 24, 2020.

[3] The recitations that follow do not constitute findings of fact, but rather are recitals attendant to the pending motions and reflect matters drawn from the complaint, the parties' briefs, and records and documents appended to the complaint and briefs.

Also at issue in this case is a CTA, which the CDC and Gilead entered into on November 1, 2004. *See* Compl. Ex. 13 at 1. That agreement was amended three times beginning in October 2006. Compl. ¶¶ 54-56. Pursuant to this agreement, Gilead was to provide antiretroviral products to the CDC for a clinical trial in Botswana. *See* Compl. Ex. 13 at 2-3. The CDC agreed in turn "not to seek patent protection in connection with any inventions that derive from the use of the Study Drug in the Trial." Compl. Ex. 13 at 2. As outlined in the amended CTA, Gilead provided the CDC with the pre-exposure prophylaxis drug Truvada and matching placebos. *See* Compl. ¶ 57.

On February 3, 2006, the CDC filed Provisional Patent Application No. 60/764,811 ("the '811 Provisional") with the U.S. Patent and Trademark Office ("PTO"). *See* Compl. Ex. 18. The '811 Provisional "related to purported inventions that [the] CDC made in the course of the research conducted under the MTAs[] and using the compounds that Gilead provided under the MTAs." Compl. ¶ 11. On January 31, 2007, the government filed non-provisional Patent Application No. 11/669,547 ("the '547 Application"). *See* Compl. Ex. 19. Gilead alleges that the "CDC relied on information derived from the Botswana clinical trial to make decisions concerning the prosecution of the '547 Application." Compl. ¶ 11. On February 1, 2008, the CDC sent Gilead a draft of an article which outlined the study described by the '649 MTA. Compl. ¶ 76. This article disclosed that five of the authors were "named in a US [g]overnment patent application related to methods for HIV prophylaxis." Compl. Ex. 20 at 1.

In January 2011, "the CDC provided interim guidelines that explicitly directed physicians to prescribe the use of" Gilead's Truvada, the drug used in the Botswana clinical trial, for pre-exposure prophylaxis. Compl. ¶ 81. A year later, in 2012, "with the encouragement and support of the [g]overnment," Gilead sought and obtained approval from the FDA to market Truvada for HIV-1 pre-exposure prophylaxis. Compl. ¶ 82. Thereafter Gilead alleges that it was not until October 2014 that CDC provided "notice to Gilead of the purported invention(s) described in the '811 Provisional and/or the '547 Application." Compl. ¶ 75; *see* Compl. Ex. 23. Subsequently, on June 2, 2015, the Patent and Trademark Office issued the first of the relevant patents, U.S. Patent No. 9,044,509 ("the '509 Patent"), from the non-provisional '547 Application. *See* Compl. ¶ 12. The government also filed U.S. Patent Application No. 15/913,750 on March 6, 2018 ("the '750 Application"). Compl. ¶ 106. Three other patents "that claim priority to the same provisional and non-provisional applications have . . . issued" since the issuance of the '509 Patent. Compl. ¶ 12.[4]

Gilead alleges that "[a]t no time during any of the communications in the course of executing the parties' obligations under the MTAs or . . . amendments was there any mention by [the] CDC of any purported invention . . . or any plan to seek patent protection as a result of the research performed . . . ." Compl. ¶ 48. Gilead further alleges that the CDC's failure to mention any "purported invention" or "any plan to seek patent protection" contravened the express terms of the CTA. Compl. ¶ 60. In 2016, after the first patent had issued, the CDC notified Gilead that it believed Truvada "may be covered by" patents "recently obtained" by the CDC. Compl. Ex. 26. The CDC suggested that Gilead apply for a non-exclusive license of the invention covered

[4] Those patents are Nos. 9,579,333 (issued Feb. 28, 2017); 9,937,191 (issued Apr. 10, 2018); and 10,335,423 (issued July 2, 2019).

by its patents. Compl. Ex. 26. Gilead responded that the government had breached the MTAs and that it did not believe the patents to be valid. Compl. ¶ 102.

On November 6, 2019, the government filed suit against Gilead in the United States District Court for the District of Delaware. Compl. ¶ 107. The government alleges in the Delaware lawsuit that Gilead infringed its patents by selling and promoting the products Truvada and a related drug, Descovy. Compl. ¶ 107. Gilead has asserted several defenses in the Delaware lawsuit, including "the equitable doctrine of unclean hands due to, among other things, the [g]overnment's breaches of the MTAs and the CTA." Compl. ¶ 27.

STANDARDS FOR DECISION

A. Rule 12(b)(1) – Lack of Subject-Matter Jurisdiction

The Tucker Act provides this court with jurisdiction over "any claim against the United States founded either upon the Constitution, or any Act of Congress or any regulation of an executive department, or upon any express or implied contract with the United States, or for liquidated or unliquidated damages in cases not sounding in tort." 28 U.S.C. § 1491(a)(1). To establish this court's jurisdiction under the Tucker Act, Gilead must "identify a substantive right for money damages against the United States separate from the Tucker Act." *Todd v. United States*, 386 F.3d 1091, 1094 (Fed. Cir. 2004) (citations omitted).

Gilead, as plaintiff, must establish jurisdiction by a preponderance of the evidence. *See Trusted Integration, Inc. v. United States,* 659 F.3d 1159, 1163 (Fed. Cir. 2011) (citing *Reynolds v. Army & Air Force Exch. Serv.,* 846 F.2d 746, 748 (Fed. Cir. 1988)). When ruling on the government's motion to dismiss for lack of jurisdiction, the court must "accept as true all undisputed facts asserted in the plaintiff's complaint and draw all reasonable inferences in favor of the plaintiff." *Id.* (citing *Henke v. United States,* 60 F.3d 795, 797 (Fed. Cir. 1995)). Moreover, "[e]very claim of which the United States Court of Federal Claims has jurisdiction shall be barred unless the petition thereon is filed within six years after such claim first accrues." 28 U.S.C. § 2501. This six-year statute of limitations "is a jurisdictional requirement attached by Congress as a condition of the government's waiver of sovereign immunity and, as such, must be strictly construed." *Dalles Irrigation Dist. v. United States*, 71 Fed. Cl. 344, 350 (2006) (quoting *Hopland Band of Pomo Indians v. United States*, 855 F.2d 1573, 1576-77 (Fed. Cir. 1988)).

Additionally, this court lacks jurisdiction over "any claim for or in respect to which the plaintiff . . . has pending in any other court . . . ." 28 U.S.C. § 1500. This statute imposes a "significant jurisdictional limitation" on this court. *United States v. Tohono O'Odham Nation*, 563 U.S. 307, 314 (2011). Section 1500 applies when two suits "are based on substantially the same operative facts, regardless of the relief sought in each suit." *Id.* at 317. "Thus, similarities or the same general subject matter do not suffice to trigger Section 1500. Rather, the specific facts at issue in the cases are determinative." *Oklahoma v. United States*, 144 Fed. Cl. 263, 272 (2019) (citing *Tohono*, 563 U.S. at 317) (additional citations omitted).

B. Rule 12(b)(6) – Failure to State a Claim Upon Which Relief Can Be Granted

Under RCFC 12(b)(6), a complaint will survive a motion to dismiss if it "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* The factual matters alleged "must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Twombly*, 550 U.S. at 555-56 (citations omitted).

When reviewing the complaint, "the court must accept as true the complaint's undisputed factual allegations and should construe them in a light most favorable to the plaintiff." *Cambridge v. United* States, 558 F.3d 1331, 1335 (Fed. Cir. 2009) (citing *Papasan v. Allain*, 478 U.S. 265, 283 (1986)) (additional citation omitted). Conclusory statements of law and fact, however, "are not entitled to the assumption of truth" and "must be supported by factual allegations." *Iqbal*, 556 U.S. at 679. "'[N]aked assertion[s]' devoid of 'further factual enhancement'" are insufficient to state a claim. *Id.* at 678 (quoting *Twombly*, 550 U.S. at 557); *accord Bradley v. Chiron Corp.*, 136 F.3d 1317, 1322 (Fed. Cir. 1998) ("Conclusory allegations of law and unwarranted inferences of fact do not suffice to support a claim.").

ANALYSIS

A. Gilead's Claims Fall Within the Six-Year Statute of Limitations Set by 28 U.S.C. § 2501

In its motion to dismiss, the government contends that Gilead's claims fall outside the six-year statute of limitations set by 28 U.S.C. § 2501. Def.'s Mot. at 8-13. It argues that Gilead's claims accrued on February 3, 2006, when the CDC filed the provisional patent application. *See id.* at 10-11. Gilead counters that its claims could not have accrued until the PTO issued the patents to the CDC. *See* Pl.'s Resp. at 9.

A claim accrues under 28 U.S.C. § 2501 "when all events have occurred to fix the [g]overnment's alleged liability, entitling the claimant to demand payment and sue here for his money." *Nager Elec. Co. v. United States*, 177 Ct. Cl. 234, 240 (1966) (footnote omitted). A viable breach of contract claim requires "four elements: 1) a valid contract between the parties; 2) an obligation or duty arising from that contract; 3) a breach of that duty; and 4) damages caused by that breach." *Claude Mayo Constr. Co., v. United States*, 132 Fed. Cl. 634, 637 (2017) (citing *San Carlos Irrigation & Drainage Dist. v. United States*, 877 F.2d 957, 959 (Fed. Cir. 1989)).

While the government filed its provisional patent application in 2006, *see* Compl. Ex. 18, and mentioned its pursuit of a patent in a draft article sent to Gilead in 2008, *see* Compl. Ex. 20, the timeliness of Gilead's claims turns on the incurrence of damages. "Because damages are a necessary element of a claim for breach of contract," Gilead's claims did not accrue until it "suffered such damages." *Lake Borgne Basin Levee Dist. v. United States*, 127 Fed. Cl. 321, 335 (2016) (citing *Terteling v. United States*, 167 Ct. Cl. 331, 338 (1964)).

Gilead alleges that "the [g]overnment's actions increased the cost of a potential license and exposed Gilead to the risk of patent-infringement damages." Compl. ¶ 110. These damages

could not have been incurred until June 2, 2015, when the PTO issued the '509 Patent to the CDC's employees. Only then did the government gain the right to enforce its patent against Gilead. *See Marsh v. Nichols, Shepherd & Co.*, 128 U.S. 605, 612 (1888) ("Until the patent is issued, there is no property right in it; that is, no such right as the inventor can enforce."). Gilead's cause of action accrued either on June 2, 2015, the date of first patent issuance, or on March 11, 2016, the date when the CDC first asserted its patent rights by notifying Gilead that Truvada "may be covered by" the CDC's patents. *See* Compl. Ex. 26. Therefore, Gilead's claims fall within the six-year statute of limitations.

B. 28 U.S.C. § 1500 Does Not Bar Gilead's Claims

The government also moves to dismiss Gilead's complaint on the grounds that the patent infringement litigation in Delaware imposes a jurisdictional bar to Gilead seeking relief in this court. *See* Def.'s Mot. at 19-22. According to the government, 28 U.S.C. § 1500 precludes this court from exercising jurisdiction over Gilead's claims, as they are "for or in respect to" Gilead's defenses in the Delaware suit. *See id.* at 19-20. Gilead argues in turn that its affirmative defense of unclean hands in the Delaware suit does not trigger Section 1500. Pl.'s Resp. at 14-15.

The Federal Circuit has interpreted Section 1500 as requiring a two-step inquiry: "(1) whether there is an earlier-filed 'suit or process' pending in another court, and, if so, (2) whether the claims asserted in the earlier-filed case are 'for or in respect to' the same claim(s) asserted in the later-filed Court of Federal Claims action." *Brandt v. United States*, 710 F.3d 1369, 1374 (Fed. Cir. 2013) (citing *Trusted Integration*, 659 F.3d at 1163-64). While it is apparent that there is a suit pending in another court, Gilead's breach-of-contract *claims* in this court are readily distinguishable from its *defenses* in the Delaware suit. Section 1500 speaks in terms of a "claim," not a defense. *See* 28 U.S.C. § 1500. Gilead has raised the affirmative defense of "unclean hands due to, among other things, the [g]overnment's breaches of the MTAs and the CTA," in the Delaware suit, Compl. ¶ 27, but it has brought its claims for breach of contract in this court only, *see* Pl.'s Resp. at 15 ("Gilead is bringing contract claims against the government in only one forum—this Court.").

The government points out that Gilead had previously "asserted four counterclaims based on the same 'unclean hands' allegations" in the Delaware suit, but Gilead dropped those counterclaims before filing suit in this court. *See* Def.'s Mot. at 19-20. The procedural posture of the Delaware suit at the time Gilead filed its action in this court is the relevant point for determining whether Section 1500 precludes this court from exercising jurisdiction. *See Central Pines Land Co. v. United States*, 697 F.3d 1360, 1365 (Fed. Cir. 2012) ("[J]urisdiction of the court depends upon the state of things at the time of the action brought.") (quoting *Grupo Dataflux v. Atlas Global Grp.*, 541 U.S. 567, 570 (2004)).

Furthermore, even if Gilead's unclean hands defense in the Delaware litigation could be characterized as a "claim" under Section 1500, Gilead's claims in this court are not "based on substantially the same operative facts" as those underlying its defense in the Delaware suit. *Tohono*, 563 U.S. at 317. The Supreme Court has clarified that analysis under Section 1500 is analogous to claim preclusion. *Id.* at 315-16. "The focus of the inquiry is the facts that give rise to the claims, not the legal theories behind the claims." *Beberman v. United States*, 755 Fed. Appx. 973, 977 (Fed. Cir. 2018) (citing *Keene Corp. v. United States*, 502 U.S. 200, 201 (1998).

While the Delaware suit and the pending case have similar factual backgrounds, the mere presence of overlapping facts is insufficient to invoke Section 1500. *See, e.g.*, *id.* at 978 (holding that there was not "enough overlap to conclude that the claims [arose] from substantially the same operative facts" because those "facts are relevant to each case for substantially different reasons"). As the Federal Circuit has noted, contemporaneous suits in a district court and the Court of Federal Claims may nevertheless be permissible when "the district court claim and the Claims Court claim [arise] out of a related sequence of facts." *Id.* at 977.

To be sure, Gilead's allegations of breach of contract serve as one of the bases for its unclean hands defense in the Delaware suit. Pl.'s Resp. at 18. In asserting this equitable defense, however, Gilead also cites the government's alleged encouragement to obtain approval from the FDA to market Truvada for HIV-1 pre-exposure prophylaxis. *See id.* at 18-19. Therefore, the district court could find the government's patents unenforceable under the equitable doctrine of unclean hands "without making any findings on whether the government breached its contractual obligations to Gilead." Pl.'s Resp. at 19. The "facts that give rise to" Gilead's breach of contract claims, therefore, are not determinative of its unclean hands defense in the Delaware suit. *Beberman*, 775 Fed. Appx. at 977. Given that Gilead did not have a "claim" pending against the government in the Delaware litigation at the time it filed suit in this court, and that the operative facts underlying its claims are distinct from those underlying its defenses, Section 1500 does not pose a jurisdictional bar to Gilead's breach of contract claims.

C. Gilead's Pleadings Are Sufficient to Survive a Motion to Dismiss Under RCFC 12(b)(6)

In addition to its argument to dismiss the complaint pursuant to RCFC 12(b)(1), the government alleges that Gilead has failed to state a claim upon which relief may be granted. Def.'s Mot. at 22-26. More specifically, the government asserts that Gilead has failed to adequately plead damages and causation. *Id.* at 23-24. Gilead argues that it has adequately pled causation and that the damages it seeks are recoverable in this court. Pl.'s Resp. at 20-31.

First, regarding Gilead's pleading of damages, according to the government, Gilead's allegations of "reputational harm" lack the required specificity, Def.'s Mot. at 23-24, and sound in tort, Def.'s Reply at 12-13. The government also points to Gilead's request for attorneys' fees as an "impermissible double recovery" for the attorneys' fees sought in the Delaware suit. Def.'s Mot. at 13-15. The factual content in Gilead's complaint, however, "allows the court to draw the reasonable inference that" Gilead has suffered damages. *Iqbal*, 556 U.S. at 570 (citation omitted). Aside from the reputational harm alleged in the complaint and the attorneys' fees sought, Gilead argues that the government's failure to disclose its patent applications and support of Gilead seeking FDA approval for Truvada "increased the cost of a potential license and exposed Gilead to the risk of patent-infringement damages." Compl. ¶ 110. The mere mention of types of damages that may not be recoverable in this suit does not invalidate Gilead's claims for breach of contract.

Moreover, Gilead is not seeking attorneys' fees pursuant to a fee-shifting statute, but "only the compensatory damages that would restore it to the position it would have been in had the government not breached the contracts . . . ." Pl.'s Resp. at 25. Attorneys' fees, "when properly categorized as compensatory damages for a contract breached by the United States and not incurred in litigation, may be recovered." *Connecticut Yankee Atomic Power Co. v. United*

States, 143 Fed. Cl. 172, 178 (2019) (internal quotation marks omitted). Gilead's request for attorneys' fees thus does not warrant dismissal.

Second, the government avers that Gilead has failed to establish but-for causation as to its theories of damages. Def.'s Mot. at 24; Def.'s Reply at 17-19. In the government's view, the links between the alleged breaches and the harm Gilead suffered are either "heavily conditional," Def.'s Mot. at 24, or absent, Def.'s Reply at 18. Construing the facts contained in the complaint "in a light most favorable to the plaintiff," *Cambridge*, 558 F.3d at 1335, however, reveals that Gilead has adequately pled causation. If the government had disclosed its plans to pursue patent protection, "Gilead would have had the opportunity to consider its options, including providing [the] CDC and/or the PTO with information showing why any such patent would be invalid." Compl. ¶ 110. The licensing dispute could "have been solved well before Gilead . . . sought an indication for [pre-exposure prophylaxis] and amplified the [g]overnment's potential royalty claims . . . ." Hr'g Tr. 36:18-20 (Dec. 14, 2020). Moreover, the government could reasonably have anticipated that Gilead would incur licensing liability and that litigation would ensue after it allegedly encouraged Gilead to apply for FDA approval to market Truvada for HIV-1 pre-exposure prophylaxis. The harm Gilead suffered as a result of the government's alleged failure to notify Gilead of its patent applications was thus foreseeable as well as direct.

Third, the government argues that the timing of the patent applications and the formation of the CTA indicate that it could not have breached the CTA. Def.'s Mot. at 25-26. The government contends that it had filed the original patent application based on "preclinical work of CDC researchers reflected in the '811 Provisional," Def.'s Reply at 7-8 & n. 5, not necessarily on the CTA and the ensuing Botswana study, using Gilead material, *id*. at 8. This argument ignores the role of the '547 Application filed in January 2007, respecting which Gilead alleges that the "CDC relied on information derived from the Botswana clinical trial to make decisions concerning the prosecution of the '547 Application," Compl. ¶ 11.[5] It also sidesteps the fact that the government filed the '750 application in 2018. Compl. ¶ 106. Gilead's claim for breach of the CTA is thus adequately pled as well.

CONCLUSION

For the reasons set forth above, the United States' motion to dismiss is DENIED. The United States shall file an answer to the complaint regarding the claims for breach of contract on or before January 27, 2021.

It is so **ORDERED**.

s/ Charles F. Lettow
Charles F. Lettow
Senior Judge

[5] The first patent, No. 9,044,509, entitled "Inhibition of HIV Infection Through Chemoprophylaxis," was issued upon the '547 Application on June 2, 2015. *See* U.S. Patent No. 9,044,509.